

Amendment No. _____

Signature of Sponsor

FILED

Date _____

Time _____

Clerk _____

Comm. Amdt. _____

AMEND Senate Bill No. 1403

House Bill No. 145*

by deleting all language after the enacting clause and substituting:

SECTION 1. Tennessee Code Annotated, Section 56-7-3113, is amended by deleting the section and substituting:

(a) A person or entity shall not administer the medication or device portion of pharmacy benefits coverage provided by a covered entity or otherwise act as a pharmacy benefits manager in this state unless the person or entity is licensed through the department of commerce and insurance.

(b) To obtain licensure as a pharmacy benefits manager, a person or entity must demonstrate to the department that the person or entity:

- (1) Is authorized to transact business in this state;
- (2) Is financially responsible, as determined by the department; and
- (3) Has not had a prior license to be a pharmacy benefits manager denied for cause or revoked by the department within five (5) years of the date on which licensure is sought.

(c)

(1) In addition to the showing required by subsection (b), a person or entity seeking licensure as a pharmacy benefits manager shall also provide the following information to the department:

(A) The person or entity's name, address, telephone number, email address, and website address; and



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(B) If the licensure is sought for an entity, the name, address, telephone number, and email address for a contact person.

(2) A material change in the information described in this subsection (c) must be filed with the department within sixty (60) days of the change.

(d)

(1) A person or entity's license as a pharmacy benefits manager must be renewed annually.

(2) In addition to the showing required by subsection (b), a person or entity seeking renewal of a license as a pharmacy benefits manager must demonstrate to the department that the person or entity complied with § 56-7-3119 during the previous licensure period.

(e)

(1) A person or entity seeking licensure as a pharmacy benefits manager shall pay a fee in the amount of one thousand dollars (\$1,000) to the department to obtain the license. A person or entity seeking renewal of a license as a pharmacy benefits manager shall pay a fee in the amount of five hundred dollars (\$500) to renew the license.

(2) Except as provided in subdivision (e)(3), the department shall use fees and fines paid pursuant to this section for purposes of administering this part.

(3) The department may use funds from fees and fines collected under this section that are in excess of the amount needed to administer this part for the purpose of promoting awareness of available substance use disorder treatment resources in this state.

(f)

(1) Failure to obtain licensure or renew a license pursuant to this section while acting as a pharmacy benefits manager in this state constitutes a violation

of this section and is punishable by a fine of two thousand five hundred dollars (\$2,500) per violation.

(2) Each day that a person or entity is in violation of subdivision (f)(1) constitutes a separate violation.

(3) A person or entity assessed a fine pursuant to this section or denied a license or renewal of a license may appeal the fine or denial pursuant to the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 2. Tennessee Code Annotated, Title 56, Chapter 7, Part 31, is amended by adding the following as new sections:

56-7-3119.

A pharmacy benefits manager shall ensure that, in the performance of pharmacy benefits management, the best interests of the insured are prioritized above the interests of other parties or entities, including, but not limited to, those of a covered entity, a pharmacy, and a pharmacist, an insurance plan, or a third party administrator.

56-7-3120.

(a) The department of commerce and insurance shall, no later than January 1, 2022, establish by rule a process to receive and process complaints from an insured, a provider, a pharmacist, or a pharmacy that allege a violation of this part by a pharmacy benefits manager.

(b) On or before January 15, 2023, and no later than January 15 each year thereafter, the department of commerce and insurance shall submit to the chief clerks of the senate and house of representatives, and to the legislative librarian, a report containing the following information from the previous calendar year:

(1) The number of complaints received against pharmacy benefits managers;

(2) Statistics on the resolution of complaints and penalties assessed against pharmacy benefits managers; and

(3) Other information and data the department deems relevant to the enforcement of this part.

(c) The department of commerce and insurance shall ensure that no personally identifying information or information protected under law is disclosed in the report required by subsection (b).

SECTION 3. Tennessee Code Annotated, Section 56-7-3105, is amended by deleting the section and substituting:

A contract entered into, amended, or renewed on or after July 1, 2021, must not contain provisions in violation of this part.

SECTION 4. The commissioner of commerce and insurance is authorized to promulgate rules to effectuate the purposes of this act. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in Tennessee Code Annotated, title 4, chapter 5.

SECTION 5. For the purpose of promulgating rules, this act takes effect upon becoming a law, the public welfare requiring it. For all other purposes, this act takes effect July 1, 2021, the public welfare requiring it, and applies to contracts entered into, amended, or renewed, and licenses issued or renewed on or after that date.

Amendment No. _____

Signature of Sponsor

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Date _____

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Clerk _____

Comm. Amdt. _____

AMEND Senate Bill No. 530

House Bill No. 635*

by deleting all language after the enacting clause and substituting:

SECTION 1. Tennessee Code Annotated, Section 39-17-430(a), is amended by deleting the subsection and substituting the following:

(1) It is unlawful for a practitioner to prescribe, order, distribute, supply, or sell an anabolic steroid for:

(A) Enhancing performance in an exercise, sport, or game without medical necessity; or

(B) Hormonal manipulation intended to increase muscle mass, strength, or weight without medical necessity.

(2) As used in this subsection (a), "medical necessity":

(A) Means:

(i) Reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent worsening of conditions in the patient that endanger life, cause suffering or pain, result in an illness or infirmity, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction; and

(ii) No other equally effective, more conservative, or substantially less costly course of treatment is available and suitable for the patient's best interest in the opinion of the examining practitioner; and

(B) Is presumed if a practitioner who has conducted a physical examination or assessment of the patient, has documented rationale and



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supportive language in the patient's medical record to support the diagnosis, treatment, and management of an ailment, disease, or illness, and has prescribed, recommended, or approved an anabolic steroid unless sufficient evidence is produced to substantiate that the anabolic steroid is not in the patient's best interest.

SECTION 2. Tennessee Code Annotated, Section 49-3-370, is amended by adding the following as a new subsection:

(e) For purposes of subdivision (a)(3), "medical necessity":

(1) Means:

(A) Reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent worsening of conditions in the patient that endanger life, cause suffering or pain, result in an illness or infirmity, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction; and

(B) No other equally effective, more conservative, or substantially less costly course of treatment is available and suitable for the patient's best interest in the opinion of the examining provider; and

(2) Is presumed if a physician who has conducted a physical examination or assessment of the patient, has documented rationale and supportive language in the patient's medical record to support the diagnosis, treatment, and management of an ailment, disease, or illness, and has prescribed, recommended, or approved an order unless sufficient evidence is produced to substantiate that the order is not in the patient's best interest.

SECTION 3. Tennessee Code Annotated, Section 50-6-124(h), is amended by deleting the subsection and substituting the following:

(1) Treatment that explicitly follows the treatment guidelines adopted by the administrator or is reasonably derived therefrom, including allowances for specific

adjustments to treatment, has a presumption of medical necessity for utilization review purposes. This presumption is rebuttable only by clear and convincing evidence that the treatment erroneously applies the guidelines or that the treatment presents an unwarranted risk to the injured worker.

(2) As used in this subsection (h), "medical necessity":

(A) Means:

(i) Reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent worsening of conditions in the patient that endanger life, cause suffering or pain, result in an illness or infirmity, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction; and

(ii) No other equally effective, more conservative, or substantially less costly course of treatment is available and suitable for the patient's best interest in the opinion of the examining healthcare provider; and

(B) Is presumed when:

(i) A healthcare provider who has conducted a physical examination or assessment of the employee, has documented rationale and supportive language in the employee's medical record to support the diagnosis, treatment, and management of an ailment, disease, or illness, and has prescribed, recommended, or approved a treatment;

(ii) The diagnosis is not covered in the treatment guidelines adopted by the administrator; and

(iii) The administrator does not produce sufficient evidence to substantiate that the treatment is not in the employee's best interest.

SECTION 4. Tennessee Code Annotated, Section 50-6-204(a)(3), is amended by deleting subdivisions (H) and (I) and substituting the following:

(H)

(1) Treatment recommended by a physician or chiropractor selected pursuant to this subdivision (a)(3), or by referral, if applicable, is presumed to be medically necessary for treatment of the injured employee.

(2) Following the adoption of treatment guidelines pursuant to § 50-6-124, the presumption of medical necessity for treatment recommended by a physician or chiropractor selected pursuant to this subsection (a), or by referral, if applicable, is rebuttable only by clear and convincing evidence demonstrating that the recommended treatment substantially deviates from, or presents an unreasonable interpretation of, the treatment guidelines.

(I) As used in this subdivision (a)(3), "medical necessity":

(1) Means:

(A) Reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent worsening of conditions in the patient that endanger life, cause suffering or pain, result in an illness or infirmity, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction; and

(B) No other equally effective, more conservative, or substantially less costly course of treatment is available and suitable for the patient's best interest in the opinion of the examining provider; and

(2) Is presumed when:

(A) A healthcare provider who has conducted a physical examination or assessment of the employee, has documented rationale and supportive language in the employee's medical record to support the diagnosis, treatment, and management of an ailment, disease, or illness, and has prescribed, recommended, or approved a treatment;

(B) The diagnosis is not covered in the treatment guidelines adopted by the administrator; and

(C) The administrator does not produce sufficient evidence to substantiate that the treatment is not in the employee's best interest.

SECTION 5. Tennessee Code Annotated, Title 53, Chapter 10, Part 1, is amended by adding the following as a new section:

53-10-114. "Medical necessity" and "medically necessary" defined.

As used in this chapter, "medical necessity" and "medically necessary":

(1) Means:

(A) Reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent worsening of conditions in the patient that endanger life, cause suffering or pain, result in an illness or infirmity, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction; and

(B) No other equally effective, more conservative, or substantially less costly course of treatment is available and suitable for the patient's best interest in the opinion of the examining provider; and

(2) Notwithstanding any law to the contrary, is presumed if a prescriber who has conducted a physical examination or assessment of the patient, has documented rationale and supportive language in the patient's medical record to support the diagnosis, treatment, and management of an ailment, disease, or illness, and has prescribed, recommended, or approved a prescription unless sufficient evidence is produced to substantiate that the prescription is not in the patient's best interest.

SECTION 6. Tennessee Code Annotated, Title 56, Chapter 1, Part 1, is amended by adding the following as a new section:

56-1-111. "Medical necessity" and "medically necessary" defined.

As used in this title, "medical necessity" and "medically necessary":

(1) Means:

(A) Reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent worsening of conditions in the patient that endanger life, cause suffering or pain, result in an illness or infirmity, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction; and

(B) No other equally effective, more conservative, or substantially less costly course of treatment is available and suitable for the patient's best interest in the opinion of the examining healthcare provider; and

(2) Notwithstanding any law to the contrary, is presumed if a healthcare provider who has conducted a physical examination or assessment of the patient, has documented rationale and supportive language in the patient's medical record to support the diagnosis, treatment, and management of an ailment, disease, or illness, and has prescribed, recommended, or approved an order unless sufficient evidence is produced to substantiate that the order is not in the patient's best interest.

SECTION 7. Tennessee Code Annotated, Section 56-6-703(7), is amended by deleting the subdivision and substituting the following:

(7) "Medical necessity" has the same meaning as defined in § 56-1-111;

SECTION 8. Tennessee Code Annotated, Section 56-7-1002(k)(2)(B), is amended by deleting the subdivision and substituting the following:

(B) For other healthcare services, "medically necessary" has the same meaning as defined in § 56-1-111.

SECTION 9. Tennessee Code Annotated, Section 56-7-1003(g)(2)(B), is amended by deleting the subdivision and substituting the following:

(B) For other healthcare services, "medically necessary" has the same meaning as defined in § 56-1-111.

SECTION 10. Tennessee Code Annotated, Section 56-7-1012(d)(2)(B), is amended by deleting the subdivision and substituting the following:

(B) For other healthcare services, "medically necessary" has the same meaning as defined in § 56-1-111.

SECTION 11. Tennessee Code Annotated, Section 56-61-102(23), is amended by deleting the subdivision and substituting the following:

(23) "Medically necessary" and "medical necessity" have the same meaning as defined in § 56-1-111;

SECTION 12. Tennessee Code Annotated, Section 63-1-164(a), is amended by adding the following as a new subdivision:

"Medical necessity":

(A) Means:

(i) Reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent worsening of conditions in the patient that endanger life, cause suffering or pain, result in an illness or infirmity, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction; and

(ii) No other equally effective, more conservative, or substantially less costly course of treatment is available and suitable for the patient's best interest in the opinion of the examining healthcare practitioner; and

(B) Notwithstanding any law to the contrary, is presumed if a healthcare practitioner who has conducted a physical examination or assessment of the patient, has documented rationale and supportive language in the patient's medical record to support the diagnosis, treatment, and management of an ailment, disease, or illness, and has prescribed, recommended, or approved an order unless sufficient evidence is produced to substantiate that the order is not in the patient's best interest.

SECTION 13. Tennessee Code Annotated, Title 63, Chapter 6, Part 2, is amended by adding the following as a new section:

63-6-248. "Medical necessity" and "medically necessary" defined.

As used in this chapter, "medical necessity" and "medically necessary":

(1) Means:

(A) Reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent worsening of conditions in the patient that endanger life, cause suffering or pain, result in an illness or infirmity, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction; and

(B) No other equally effective, more conservative, or substantially less costly course of treatment is available and suitable for the patient's best interest in the opinion of the examining healthcare provider; and

(2) Notwithstanding any law to the contrary, is presumed if a healthcare provider licensed pursuant to this chapter, who has conducted a physical examination or assessment of the patient, has documented rationale and supportive language in the patient's medical record to support the diagnosis, treatment, and management of an ailment, disease, or illness, and has prescribed, recommended, or approved an order unless sufficient evidence is produced to substantiate that the order is not in the patient's best interest.

SECTION 14. Tennessee Code Annotated, Section 63-10-204, is amended by adding the following as a new subdivision:

"Medical necessity" and "medically necessary":

(A) Means:

(i) Reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent worsening of conditions in the patient that endanger life, cause suffering or pain, result in an illness or infirmity, threaten to

cause or aggravate a handicap, or cause physical deformity or malfunction; and

(ii) No other equally effective, more conservative, or substantially less costly course of treatment is available and suitable for the patient's best interest in the opinion of the examining prescriber; and

(B) Notwithstanding any law to the contrary, is presumed if a prescriber who has conducted a physical examination or assessment of the patient, has documented rationale and supportive language in the patient's medical record to support the diagnosis, treatment, and management of an ailment, disease, or illness, and has prescribed, recommended, or approved an order unless sufficient evidence is produced to substantiate that the order is not in the patient's best interest.

SECTION 15. Tennessee Code Annotated, Section 68-1-128, is amended by adding the following as a new subsection:

(j) As used in this section, "medically necessary":

(1) Means:

(A) Reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent worsening of conditions in the patient that endanger life, cause suffering or pain, result in an illness or infirmity, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction; and

(B) No other equally effective, more conservative, or substantially less costly course of treatment is available and suitable for the patient's best interest in the opinion of the examining prescriber; and

(2) Notwithstanding any law to the contrary, is presumed if a prescriber who has conducted a physical examination or assessment of the patient, has documented rationale and supportive language in the patient's medical record to

support the diagnosis, treatment, and management of an ailment, disease, or illness, and has prescribed, recommended, or approved an order unless sufficient evidence is produced to substantiate that the order is not in the patient's best interest.

SECTION 16. Tennessee Code Annotated, Section 68-11-210(d), is amended by deleting the subsection and substituting the following:

(d)

(1) If a violation, citation, deficiency, or civil monetary penalty is found during the nursing home survey process, in which the violation is based upon an action or actions that are directly pursuant to a physician's order, then the board of medical examiners' consultant, or the consultant's physician designee, must be contacted for a consultation on the determination as to the medical necessity of the physician's order in question.

(2) The determination of medical necessity must:

(A) Be based upon the recognized medical standards of practice and include, but not be limited to, a review of the physician's order, the date the order was given, the status of the patient at the time the actions occurred and the outcomes of the actions, and applicable state and federal regulations; and

(B) Include contact between:

(i) The consultant or designee; and

(ii) The treating physician or the facility's medical director.

(3) A consultation between the consultant or designee and the treating physician or medical director must be completed within the time frames of the survey process.

(4) If it is determined that the violation is based upon or relates to a physician's order determined to be medically necessary, then a violation, citation,

deficiency, or civil monetary penalty shall not be assessed against the facility and a deficiency cited in violation of this subsection (d) must be removed.

(5) The department shall report back to the board of medical examiners and the appropriate standing committees at the end of six (6) months regarding the effectiveness and the resources necessary to meet the requirements of this subsection (d).

(6) As used in this subsection (d), "medical necessity" and "medically necessary":

(A) Means:

(i) Reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent worsening of conditions in the patient that endanger life, cause suffering or pain, result in an illness or infirmity, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction; and

(ii) No other equally effective, more conservative, or substantially less costly course of treatment is available and suitable for the patient's best interest in the opinion of the examining physician; and

(B) Notwithstanding subdivision (d)(2), is presumed if a physician who has conducted a physical examination or assessment of the patient, has documented rationale and supportive language in the patient's medical record to support the diagnosis, treatment, and management of an ailment, disease, or illness, and has prescribed, recommended, or approved an order unless sufficient evidence is produced to substantiate that the order is not in the patient's best interest.

SECTION 17. Tennessee Code Annotated, Section 68-11-232, is amended by deleting the section and substituting the following:

(a) This chapter does not require or authorize:

(1) The state medicaid agency or a managed care organization to approve, supply, or cover the services set out in § 68-11-201 for assisted-care living facilities;

(2) The state medicaid agency or a managed care organization to approve, supply, or cover medically necessary home care services provided in an assisted-care living facility, where the home care services are provided, supervised, or directed by any person or entity with an ownership or control interest or by a managing employee of an entity with an ownership or control interest in the licensed assisted-care living facility or a licensed nursing home; or

(3) A third-party payer to approve, supply, or cover medically necessary home care services provided in an assisted-care living facility, where the home care services are provided, supervised, or directed by any person or entity with an ownership or control interest or by a managing employee of an entity with an ownership or control interest in the licensed assisted-care living facility or a licensed nursing home.

(b) As used in this section, "medically necessary":

(A) Means:

(i) Reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent worsening of conditions in the patient that endanger life, cause suffering or pain, result in an illness or infirmity, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction; and

(ii) No other equally effective, more conservative, or substantially less costly course of treatment is available and suitable for the patient's best interest in the opinion of the examining healthcare provider; and

(B) Notwithstanding subsection (a), is presumed if a healthcare provider who has conducted a physical examination or assessment of the patient, has documented rationale and supportive language in the patient's medical record to support the diagnosis, treatment, and management of an ailment, disease, or illness, and has prescribed, recommended, or approved an order unless sufficient evidence is produced to substantiate that the order is not in the patient's best interest.

SECTION 18. Tennessee Code Annotated, Section 68-32-101(a)(2)(A), is amended by adding the following as a new subdivision:

(iii) "Medical necessity," within the scope of this section:

(a) Means:

(1) Reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent worsening of conditions in the patient that endanger life, cause suffering or pain, result in an illness or infirmity, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction; and

(2) No other equally effective, more conservative, or substantially less costly course of treatment is available and suitable for the patient's best interest in the opinion of the examining healthcare provider; and

(b) Is presumed if a healthcare provider who has conducted a physical examination or assessment of the patient, has documented rationale and supportive language in the patient's medical record to support the diagnosis, treatment, and management of an ailment, disease, or illness, and has prescribed, recommended, or approved an order unless sufficient evidence is produced to substantiate that the order is not in the patient's best interest.

SECTION 19. Tennessee Code Annotated, Section 71-5-103, is amended by adding the following as a new subdivision:

"Medical necessity" and "medically necessary":

(A) Means:

(i) Reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent worsening of conditions in the patient that endanger life, cause suffering or pain, result in an illness or infirmity, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction; and

(ii) No other equally effective, more conservative, or substantially less costly course of treatment is available and suitable for the patient's best interest in the opinion of the examining healthcare provider; and

(B) Notwithstanding § 71-5-144, is presumed if a healthcare provider who has conducted a physical examination or assessment of the patient, has documented rationale and supportive language in the patient's medical record to support the diagnosis, treatment, and management of an ailment, disease, or illness, and has prescribed, recommended, or approved an order unless sufficient evidence is produced to substantiate that the order is not in the patient's best interest;

SECTION 20. Tennessee Code Annotated, Section 71-5-501, is amended by adding the following as a new subdivision:

"Medically necessary":

(A) Means:

(i) Reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent worsening of conditions in the patient that endanger life, cause suffering or pain, result in an illness or infirmity, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction; and

(ii) No other equally effective, more conservative, or substantially less costly course of treatment is available and suitable for the patient's best interest in the opinion of the examining healthcare provider; and

(B) Is presumed if a healthcare provider who has conducted a physical examination or assessment of the patient, has documented rationale and supportive language in the patient's medical record to support the diagnosis, treatment, and management of an ailment, disease, or illness, and has prescribed, recommended, or approved an order unless sufficient evidence is produced to substantiate that the order is not in the patient's best interest;

SECTION 21. The headings to sections in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 22. This act takes effect July 1, 2021, the public welfare requiring it, and applies to determinations of medical necessity and medically necessary occurring on or after that date.